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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,422	09/27/2001	Kimberly A. Spytek	21402-132 (CURA 432)	3633

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,422	SPYTEK ET AL.	
	Examin r	Art Unit	
	MICHAEL BRANNOCK	1646	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 25 September 2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-52 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-4, 38, and 41**, drawn to an isolated polypeptide, pharmaceutical compositions, and kits comprising same, classified in class 530, subclass 300, for example.

II. Claims **5-14, 39, and 42**, drawn to an isolated nucleic acid molecule, vectors, host cells, pharmaceutical compositions, and kits comprising same, classified in class 435, subclass 325, for example.

III. Claims **15-17, 40, and 43**, drawn to an antibody, pharmaceutical compositions, and kits comprising same, classified in class 530, subclass 387.1, for example.

IV. Claim **18**, drawn to a method for determining the presence or amount of a polypeptide, classified in class 435, subclass 7.1, for example.

V. Claims **19-21**, drawn to a method for determining the presence or amount of a nucleic acid molecule, classified in class 435, subclass 6, for example.

VI. Claims **22-23**, drawn to a method of identifying an agent that binds to a *polypeptide*, classification dependent upon agent structure.

VII. Claim **24**, drawn to a method for identifying an agent that modulates the expression or activity of a *polypeptide*, classification dependent upon agent structure.

VIII. Claim **25**, drawn to a method for modulating the activity of a *polypeptide*, classification dependent upon compound structure.

IX. Claims **26-29 and 48**, drawn to a method of treating or preventing a GPCRX-associated disorder, said method comprising administering to a subject a *polypeptide*, classified in class 514, subclass 2, for example.

X. Claims **30-33**, drawn to a method of treating or preventing a GPCRX-associated disorder, said method comprising administering to a subject a *nucleic acid molecule*, classified in class 514, subclass 44, for example.

XI. Claims **34-37 and 49**, drawn to a method of treating or preventing a GPCRX-associated disorder, said method comprising administering to a subject an *antibody*, classified in class 424, subclass 130.1, for example.

XII. Claims **44-45**, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of a *polypeptide*, classification dependent upon how said polypeptide levels are determined.

XIII. Claims **46-47**, drawn to a method for determining the presence of or predisposition to a disease associated with altered levels of a *nucleic acid molecule*, classification dependent upon how said polypeptide levels are determined.

XIV. Claims **50-51**, drawn to a method for the screening of a candidate substrate interacting with an olfactory receptor polypeptide, classification dependent upon candidate substrate structure.

XV. Claims **52**, drawn to a method for screening of ligand molecules interacting with an olfactory receptor polypeptide said method comprises providing an adenovirus

containing a nucleic acid encoding a polypeptide and infecting an olfactory epithelium with said adenovirus, classified in class 800, subclass 3, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, and III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

4. The polypeptide of Invention I can be prepared by processes which are materially different from the nucleic acid molecule of Invention II or the antibody of Invention III, such as by chemical synthesis.

5. Additionally, the nucleic acid molecule of Invention II can be used other than to make the polypeptide of Invention I, such in gene therapy or as a probe in nucleic acid hybridization assays. The antibody of Invention III is not required to make or use the nucleic acid molecule of Invention II.

6. Finally, although the antibody of Invention III can be used to obtain the polypeptide of Invention I, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The nucleic acid molecule of Invention II is not required to make or use the antibody of Invention III.

7. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions IV, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, and XV are directed to methods that are distinct both physically and functionally, and are not required one for the other.

8. Invention IV requires search and consideration of determining the presence or amount of a *polypeptide* in a sample, which is not required by any of the other Inventions. Invention V requires search and consideration of determining the presence or amount of a *nucleic acid molecule* in a sample, which is not required by any of the other Inventions.

9. Invention VI requires search and consideration of identifying an agent that binds to a *polypeptide*, which is not required by any of the other Inventions. Invention VII requires search and consideration of identifying an agent that modulates the expression or activity of a *polypeptide*, which is not required by any of the other Inventions. Invention VIII requires search and consideration of modulating the activity of a *polypeptide*, which is not required by any of the other Inventions.

10. Invention IX requires search and consideration of treating or preventing a GPCRX-associated disorder comprising administering a *polypeptide*, which is not required by any of the other Inventions. Invention X requires search and consideration of treating or preventing a GPCRX-associated disorder comprising administering a *nucleic acid molecule*, which is not required by any of the other Inventions. Invention XI requires search and consideration of

treating or preventing a GPCRX-associated disorder comprising administering an *antibody*, which is not required by any of the other Inventions.

11. Invention XII requires search and consideration of determining the presence of or a predisposition to a disease associated with altered levels a *polypeptide*, which is not required by any of the other Inventions. Invention XIII requires search and consideration of determining the presence of or a predisposition to a disease associated with altered levels a *nucleic acid molecule*, which is not required by any of the other Inventions.

12. Invention XIV requires search and consideration of screening a candidate substrate interacting with an olfactory receptor polypeptide, which is not required by any of the other Inventions. Invention XV requires search and consideration of infecting olfactory epithelium with an adenovirus, which is not required by any of the other Inventions.

13. Inventions VI and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibody of Invention III could be made through materially different means such as immunization of an animal with the polypeptide of Invention I.

14. Inventions I and each of IV, VI, VII, VIII, IX, XII, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the *polypeptide* of

Invention I can be used in materially different methods such as making the antibody of Invention III via immunization of animals with said polypeptide.

15. Inventions II and each of V, X, XIII, and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the *nucleic acid molecule* of Invention II can be used in materially different methods such as to make a transgenic animal.

16. Inventions III and each of IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used in materially different methods such as to purify the polypeptide of Invention I from natural sources.

17. Inventions I and each of V, X, XI, XIII, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions I and each of V, X, XI, XIII, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V, X, XI, XIII, and XV do not recite the use or production of the *polypeptide* of Invention I.

18. Inventions II and each of IV, VI, VII, VIII, IX, XI, XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of IV, VI, VII, VIII, IX, XI, XII, and XIV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions IV, VI, VII, VIII, IX, XI, XII, and XIV do not recite the use or production of the *nucleic acid molecule* of Invention II.

19. Inventions III and each of V, VII, VIII, IX, X, XII, XIII, XIV, and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions III and each of V, VII, VIII, IX, X, XII, XIII, XIV, and XV are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions V, VII, VIII, IX, X, XII, XIII, XIV, and XV do not recite the use or production of the *antibody* of Invention III.

20. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 1.

B. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 2.

C. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 3.

D. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 4.

E. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 5.

F. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 6.

G. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 7.

H. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 8.

I. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 9.

J. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 10.

K. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 11.

L. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 12.

M. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 13.

N. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 14.

O. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 15.

P. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 16.

Q. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 17.

R. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 18.

S. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 19.

T. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 20.

U. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 21.

V. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 22.

W. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 23.

X. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 24.

Y. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 25.

Z. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 26.

AA. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 27.

BB. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 28.

CC. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 29.

DD. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 30.

EE. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 31.

FF. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 32.

GG. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 33.

HH. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 34.

II. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 35.

JJ. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 36.

KK. Claims **1-52**, each in part, as the inventions pertains to SEQ ID NO: 37.

LL. Claims **1-52**, each in part, as the inventions pertain to SEQ ID NO: 38.

21. The inventions are distinct, each from the other because of the following reasons:

22. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to <u>different</u> products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Inventions A-LL are directed to sequences that are distinct both physically and functionally, and are not required one for the other. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains to all sequences would therefore present the examiner with an undue search burden.

23. Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect one group from I-XV. In order to be fully responsive, Applicant must elect one group from I-XV and one group from A-LL.

24. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael Brannock** whose telephone number is **(703) 306-5876.** The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Yvonne Eyler, Ph.D.** can be reached on **703-308-6564**. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 30, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600